

# 510(k) Summary

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## SUBMITTED FOR:

**Company Name:** Proxy Biomedical, Ltd.  
**Address:** Coilleach, Spiddal  
Galway, IRELAND  
Caitriona Conneely, Quality Assurance Manager  
Tel: 353 91 896900

**Submitted by:** Elaine Duncan, M.S.M.E., RAC  
President, Paladin Medical, Inc.  
PO Box 560  
Stillwater, MN 55082  
715-549-6035  
715-549-5380

**CONTACT PERSON:** Elaine Duncan  
**DATE PREPARED:** September 4, 2012 (revised)  
**TRADE NAME:** Polyform™ Synthetic Mesh  
**COMMON NAME:** Surgical Mesh  
**PROCEDURE:** OTO  
**CLASS/REGULATION:** Class II/21 CFR878.3300  
**FDA REVIEW PANEL:** Obstetrics/Gynecology

**SUBSTANTIALLY EQUIVALENT TO:** Polyform™ Synthetic Mesh is substantially equivalent to the Mersilene Mesh (Ethicon, Inc.), the Prolene Soft Mesh (Ethicon, Inc.), and the Bard Mesh (C.R. Bard, Inc.) a polypropylene mesh.

## DESCRIPTION of the DEVICE:

Polyform™ Synthetic Mesh is intended to be utilized for surgical procedures pertaining to the pelvic floor. Polyform Synthetic Mesh is supplied sterile and provided in sheet form to be cut to size and sutured by the surgeon to meet the individual patient's needs. Polyform Synthetic Mesh is manufactured from monofilament polypropylene fibers.

## INDICATIONS FOR USE:

Polyform™ Synthetic Mesh is indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor via an abdominal approach, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

## SUMMARY of TESTING:

Bench test data reveal Polyform™ Synthetic Mesh has mechanical and material characterization values that are substantially equivalent to the predicate devices. The biocompatibility test results show that the material used in the design and manufacture of the device is non-toxic and non-sensitizing to biological tissues consistent with their intended use. Updated test data on the bench and the rodent, as summarized in the updated product brochure, shows comparable technical properties to the more contemporary material properties like those in the Gynemesh PS.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-002

OCT 26 2012

Proxy BioMedical, Ltd.  
% Elaine Duncan, M.S.M.E., RAC  
President  
Paladin Medical Incorporated  
P.O. Box 560  
STILLWATER MN 55082-0560

Re: K051245  
Trade/Device Name: Polyform™ Synthetic Mesh  
Regulation Number: 21 CFR § 878.3300  
Regulation Name: Surgical Mesh  
Regulatory Class: II  
Product Code: OTO  
Dated (Date on orig SE ltr): May 11, 2005  
Received (Date on orig SE ltr) : May 16, 2012

Dear Ms. Duncan:

This letter corrects our substantially equivalent letter of June 17, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

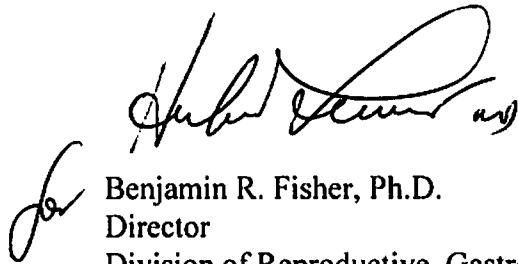
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher", is written over a large, stylized "for" in cursive.

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K051245

Device Name: Polyform™ Synthetic Mesh

### Indications for Use:

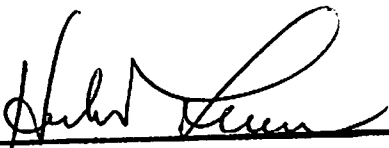
Polyform™ Synthetic Mesh is indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor via an abdominal approach, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Prescription Use   X   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
510(k) Number   K051245

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210(k) Number \_\_\_\_\_  
Urological Devices  
Division of Reproductive, Gastro-Renal, and  
(Division Sign-Off)

10/15/72